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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,853	01/11/2001	James Berger Camden	7487RD	9597

30113 7590 09/24/2003

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	8

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/758,853	Camden et al.
Examiner	**Art Unit**
Phyllis G. Spivack	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 20-44 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 20-44 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1/2,5,6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicants' Preliminary Amendment filed January 11, 2001, Paper No. 7, is acknowledged. Claims 1-19 are canceled. New claims 28-44 are presented. Accordingly, claims 20-44 are now under consideration.

Three Information Disclosure Statements filed January 11, 2001, May 31, 2001 and June 4, 2001, respectively, Paper Nos. 1 ½, 5 and 6, are further acknowledged and have been reviewed to the extent each is a proper citation on a U.S. patent. S.N. 09/538006 is the parent application of the present case.

Claims 23, 39, 40, 43 and 44 are objected to under 37 C FR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claim 23 does not further limit the subject matter of claim 22.

Claims 39, 40, 43 and 44 are directed to intended uses of a pharmaceutical composition. As such, they do not confer patentable weight to the claims. See In re Hack, 114 USPQ 161.

The Amendment filed January 11, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: On page 9 of the Amendment, the introduction of the term "virus" is new matter. The amendment introduced to page 32 of the specification, Example 10, beginning on line 24, constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 21, 22, 33, 34, 28, 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 21, 22, 33, 34, 28 and 29 recite the limitation "(said) pharmaceutical addition salt(s)". There is insufficient antecedent basis for this limitation in independent claims 20 and 32.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-25, 28, 29, 32-34 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauel et al., DE 3722992.

Hauel teaches a pharmaceutical composition in the form of a tablet comprising 1H-imidazo[4,5-b]pyridine, 2-(2-thienyl)-monochloride. See Example 22 on page 10. See page 6, lines 48-49, where dosages are disclosed, as required by claim 21, 23 and 37. The pharmaceutically acceptable salt in the form of a chloride and lactose as part of the pharmaceutical carrier in solid form are disclosed. The intended use of a composition claim confers no patentable weight to the claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauel et al., DE 3722992.

Hauel teaches a solid pharmaceutical composition comprising 1H-imidazo[4,5-b]pyridine, 2-(2-thienyl)-monochloride. See Example 22 on page 10. See page 6, lines 48-49, where dosages are disclosed, as required by claim 21, 23 and 37. The pharmaceutically acceptable salt in the form of a chloride and lactose as part of the pharmaceutical carrier in solid form are disclosed. The intended use of a composition claim confers no patentable weight to the claim. The claims differ in that various, conventional dosage forms are not disclosed by Hauel. However, one having ordinary skill in the art would have been motivated to prepare a solid or liquid dosage form, as well as a liposome delivery system, in view of the teachings of Hauel. Such modification would have been obvious in the absence of evidence to the contrary because the skilled artisan in formulation chemistry, in view of the efficacy of a particular dosage form, would have been motivated to prepare alternative dosage forms with a reasonable expectation of efficacy. Further, multiple drug therapy to treat a wide range of pathologies - in this case, virology - is a common therapeutic approach. The selection of an additional therapeutic agent is a parameter well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

September 16, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER